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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/736,267	10/24/96	BACKSTROM	K 06275/004001

EXAMINER

HM12/0405

LUKTON, D

ART UNIT	PAPER NUMBER
1653	37

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DATE MAILED: 04/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev.11/00)

Office Action Summary

Application No.	Applicant(s)
08/736,267	Backstrom
Examiner	**Group Art Unit**
David Lukton	1653

☒ Responsive to communication(s) filed on *Jan 16, 2001*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-10, 12-16, 21, 22, 26-32, 50-97, and 101-118* is/are pending in the applicat

Of the above, claim(s) *2, 21, 22, 26-30, 32, 50-97, and 103* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 3-10, 12-16, 31, 101, 102, and 104-118* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Pursuant to the directives of paper No. 36 (filed 1/16/01), claims 1, 2, 12, 13, 16, 31 have been amended, and claims 102-118 added. Claims 1-10, 12-16, 21, 22, 26-32, 50-97, 101-118 are pending. Claims 2, 21, 22, 26-30, 32, 50-97 remain withdrawn from consideration; claim 103 is also withdrawn. Claims claims 1, 3-10, 12-16, 31, 101, 102, 104-118 are examined (in part) in this Office action.

Applicants' arguments filed 1/16/01 have been considered and found persuasive in part:

- The rejection of claims 1, 3-10, 101 over Durani (WO 91/16882) is withdrawn, although the rejection of claim 12 over Durani is maintained.
- The rejection of claims 1, 3-10, 101 over Illum (USP 5,707,644) is withdrawn, although the rejection of claim 12 over Illum is maintained.
- The rejection of claims 1, 3-10, 12, 101 over Patton (USP 5,607,915) is withdrawn
- The rejection of claims 1, 3-10, 12-16, 31, 101 over Patton in view of (secondary references) is withdrawn.

*

Claims 1 and 102 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 42 of copending application Serial No. 08/960,093. Although the conflicting claims are not identical, they are not patentably distinct from each other.

[This is a *provisional* obviousness-type double patenting rejection because the conflicting

claims have not in fact been patented]

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application . See 37 CFR 1.78(d)

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The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-10, 12-16, 31, 101, 102, 104-118 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, hac possession of the claimed invention.

Claim 1 has been amended to recite that each chain of the double-chain phospholipid is 8 or fewer carbon atoms in length. This is regarded as new matter, but only because double-chain phospholipids in which the fatty acid portion consists of nine carbon atoms are excluded. It is suggested that claims 1 and 102 be amended to recite that the length of each chain is fewer than 10 carbon atoms; this can be alternatively stated as 9 carbon atoms or fewer.

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Claims 1, 3-10, 12-16, 31, 101, 102, 104-118 are rejected under 35 U.S.C. §112 second

paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the diameter of the particles can be "less than about" 10 microns; the same is recited in claim 102. This renders the claims indefinite. Probably the following would be sufficient:

the diameter is less than 10 microns, or equal to about 10 microns.

(See also claims 2 and 79).

*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2) and (4) of section 371(c) of this title before the invention thereof by the applicant for the patent.

Claims 1, 3-10, 12, 101-112, 117 are rejected under 35 U.S.C. §102(b) as being anticipated by Wang (USP 5,011,678).

Wang teaches dry powders comprising insulin and various steroids such as STDHF (STDHF is defined at col 8, line 10). Also taught is a particle size of of 2-8 microns.

The rejected claims encompass a mixture of a peptide and a "derivative" of a bile salt. The issue here is that which might be meant by a "derivative" of a bile salt. This ground of rejection is predicated on the assertion that the steroids disclosed by Wang constitute derivatives of bile salts.

Thus, the claims are anticipated

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Claims 12, 102, 104-111, 118 are rejected under 35 U.S.C. §102(e) as being anticipated by Illum (USP 5,707,644).

As indicated previously (Paper No. 24, mailed 4/28/98), Illum teaches a dry composition comprising microparticles that are less than 10 microns in size, which composition also contains peptides and enhancers. This ground of rejection is maintained, since the compositions of the reference can contain phospholipids; instant claim 12 permits phospholipids of any constitution.

As for claim 102, applicants have preemptively argued that the intended use of the Illum compositions is different. However, Illum teaches that a preferred ingredient is starch (col 3, line 31+). On page 15, line 6 of the specification, it is stated that starch can be used. Accordingly, whatever properties, advantageous or disadvantageous, are accorded by the starch will be common to both compositions.

The rejection is maintained.

*

Claims 12 and 112 are rejected under 35 U.S.C. §102(b) as being anticipated by Durani (WO 91/16882).

The teachings of the reference were indicated previously (Paper No. 24, mailed 4/28/98). Applicants have argued that by imposing an upper limit of 8 carbon atoms on the length of the fatty acids (which make up the phospholipids), they have circumvented the teachings of the reference. This point is not in dispute. The issue, instead, is whether or not the structural limits on the phospholipid extend to claim 12. It is suggested that applicants amend claim 12 to re-affirm the structural limitations recited in claim 1.

✷

- With regard to the restriction between Groups I and II, applicants are invited to comment on the validity of a rejection of claims 2 and 103 over Sekine (JP 632932), which teaches a particle size of 10-250 microns. Claims 2 and 103 permit particles with a diameter of greater than 10 microns. Although claims 2 and 103 require the presence of 10 micron particles, there is no lower limit to the percent of the total particles that must be 10 microns or less. Thus, claims 2 and 103 would encompass compositions in which 99.99% of the particles are greater than 10 microns. This reference may be used to justify a decision not to rejoin these claims.

- Reference "AJ" was stricken from the IDS because of the absence of a translation; reference "AD" was stricken because it was not received.

- Three Japanese patents were stricken from the IDS. The record should be made clear that the full patent was never considered (no translation was provided). Applicants should resubmit an IDS and list e.g., the following ounder "Other Documents":

  Abstract of JP 4,041,421

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800